

Remarks

The Final Office Action of September 10, 2004 has been reviewed and its contents carefully noted. Reconsideration of this case, as amended, is earnestly requested. Claims 1-46 remain in this case, claims 1 and 43 being amended by this response. The amendment of claims 1 and 43 is supported throughout the specification, and particularly at page 3, lines 2-3, and page 4, lines 28-29, for example; no new matter has been added.

Entry of this amendment is earnestly requested, as it is believed: 1) to place the entire application in condition for allowance, 2) not to raise any new issues or require further search, 3) to be directly responsive to the Final Office Action, and 4) to place the application in even better form for appeal, should such appeal be necessary.

In view of the above amendments and the following remarks, favorable reconsideration of the Final Office Action is respectfully requested.

Allowable Subject Matter

Applicant gratefully acknowledges Examiner's statement that claims 35-42 are allowed.

Claims 21, 25, 27 and 34 were objected to as being dependent upon a rejected base claim, but the Examiner indicated that they would be allowable, if rewritten in independent form, including all of the limitations of the base claim and any intervening claims.

Applicant gratefully acknowledges Examiner's statement that claims 21, 25, 27 and 34 are allowable. However, Applicant defers amendment at this time, as the rejection of independent claim 1, from which claims 21, 25, 27 and 34 depend, is hereby respectfully traversed.

It is respectfully submitted that the objection is thus overcome. Reconsideration and withdrawal of the objection to claims 21, 25, 27 and 34 are therefore earnestly requested.

Rejections Under 35 U.S.C. § 102

Claims 1-4, 7-8, 10-11, 13, 15-19, 22-24, 26, 28-33 and 43-46 were finally rejected under 35 U.S.C. § 102(b) as being anticipated by White (US 5,431,916). It is respectfully submitted that the rejection is overcome by the amendment of claims 1 and 43.

White (US 5,431,916) teaches the use of a tri-ester and polyvinylpyrrolidone (PVP), and optionally polyethylene glycol (PEG), as solvent for pharmaceutical drugs which are to be encapsulated into soft gelatin capsules. White clearly teaches that the bitter taste and

aroma of a bitter drug can be masked because it is encapsulated in a soft gelatin capsule, which prevents the consumer from tasting the drug, while the soft gelatin capsule is in the mouth, because the bitter drug does not contact the tongue. See White at Column 1, lines 26-33. White also teaches that tri-esters are bitter. See White at Column 1, lines 21-24.

In improving the taste of a liquid pharmaceutical composition or an extemporaneously prepared liquid pharmaceutical composition for direct oral ingestion, a person of ordinary skilled in the art would not use a known bitter excipient. In other words, one does not try to improve the taste of a bitter drug by adding a known bitter ingredient/excipient, such as a tri-ester.

Applicant's independent claim 1, as amended, and independent claim 43, as amended, recite, *inter alia*, a taste-masked liquid pharmaceutical composition administered to a patient as a liquid, said liquid having a substantially non-bitter taste. White does not disclose such a composition or any method for preparing it. Rather, the pharmaceutical compositions disclosed by White clearly are bitter-tasting (due at least in part to the presence of the tri-ester), as attested to in the Declaration of Dr. Kennie U. Dee, Ph.D., already of record in the present application. Indeed, all of the examples disclosed by White are necessarily bitter compositions, as described by White at Column 3, line 21-24: “An essential component of the present compositions is a tri-ester. Tri-esters are generally clear, viscous liquids with a bitter taste and low toxicity.” Further data to support the bitterness of tri-esters in liquid pharmaceutical compositions is found in Exhibit 2 of the Declaration of Dr. Kennie U. Dee, Ph.D., already of record.

Therefore, White does not disclose each and every limitation of Applicant's independent claims 1 and 43, because White does not teach any non-bitter composition, and thus the reference cannot anticipate the claims. It is respectfully submitted that the rejection of claims 1 and 43 as being anticipated by White is thus overcome. Reconsideration and withdrawal of the rejection are therefore earnestly requested.

It is respectfully submitted that the rejection is overcome by the amendment of claims 1 and 43. Reconsideration and withdrawal of the rejection are therefore earnestly requested.

Dependent claims 2-4, 7-8, 10-11, 13, 15-19, 22-24, 26, 28-33 and 44-46, being dependent upon and further limiting independent claims 1 and 43, should be allowable for that reason, as well as for the additional limitations recited therein. Reconsideration and

withdrawal of the rejection of claims 1-4, 7-8, 10-11, 13, 15-19, 22-24, 26, 28-33 and 43-46 as being anticipated by White are respectfully requested.

**Rejections Under 35 U.S.C. § 103**

Claims 5, 6, 9, 12, 14 and 20 were finally rejected under 35 U.S.C. § 103(a) as being obvious over White (US 5,431,916). Applicant respectfully disagrees with the rejection.

Applicant respectfully disagrees, and maintains that the claims, as amended, are patentable over White, for the reasons given above in respect to the section 102 rejection of independent claim 1, from which claims 5, 6, 9, 12, 14 and 20 depend. The arguments above as to the novelty of claim 1 are repeated here by reference. It is respectfully submitted that the rejection is thus overcome. Reconsideration and withdrawal of the rejection of claims 5, 6, 9, 12, 14 and 20 as being obvious over White are respectfully requested.

Further, there is no teaching in the prior art of record that one of ordinary skill in the art would be motivated to modify White, or would have a reasonable expectation of success in modifying White, as suggested by the Examiner. See Declaration of Dr. Kennie U. Dee, Ph.D. Thus, White does not teach or suggest Applicant's invention as recited in claim 1.

Dependent claims 5, 6, 9, 12, 14 and 20, being dependent upon and further limiting independent claim 1, should be allowable for that reason, as well as for the additional limitations recited therein. Reconsideration and withdrawal of the rejection of claims 5, 6, 9, 12, 14 and 20 as being obvious over White are therefore respectfully requested.

**Conclusion**

Based upon the above Amendments, Remarks and the papers of record, Applicant believes that the pending claims of the above-captioned application are in allowable form and patentable over the prior art of record. Applicant respectfully requests reconsideration of the pending claims 1-46 and a prompt Notice of Allowance thereon.

Applicant believes that no extension of time is necessary to make this Response timely. Should Applicant be in error, Applicant respectfully requests that the Office grant such time extension pursuant to 37 C.F.R. § 1.136(a) as necessary to make this Response timely, and hereby authorizes the Office to charge any necessary fee or surcharge with respect to said time extension to the deposit account of the undersigned firm of attorneys, Deposit Account No. 50-0289.



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Respectfully submitted,  
WALL MARAJMA & BILINSKI

A handwritten signature in black ink, appearing to read "Thomas T. Aquilla".

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